

reagents used to measure by immunochemical techniques the inter-*alpha* trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-*alpha* trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 53 FR 11253, Apr. 6, 1988; 65 FR 2313, Jan. 14, 2000]

Subpart G—Tumor Associated Antigen immunological Test Systems

§866.6010 Tumor-associated antigen immunological test system.

(a) *Identification*. A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification*. Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled "Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s to FDA," and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec.

868.1 Scope.

868.3 Effective dates of requirement for premarket approval.

868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

- 868.1030 Manual algesimeter.
- 868.1040 Powered algesimeter.
- 868.1075 Argon gas analyzer.
- 868.1100 Arterial blood sampling kit.
- 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.
- 868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO2}) analyzer.
- 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.
- 868.1200 Indwelling blood oxygen partial pressure (P_{O2}) analyzer.
- 868.1400 Carbon dioxide gas analyzer.
- 868.1430 Carbon monoxide gas analyzer.
- 868.1500 Enflurane gas analyzer.
- 868.1575 Gas collection vessel.
- 868.1620 Halothane gas analyzer.
- 868.1640 Helium gas analyzer.
- 868.1670 Neon gas analyzer.
- 868.1690 Nitrogen gas analyzer.
- 868.1700 Nitrous oxide gas analyzer.
- 868.1720 Oxygen gas analyzer.
- 868.1730 Oxygen uptake computer.
- 868.1750 Pressure plethysmograph.
- 868.1760 Volume plethysmograph.
- 868.1780 Inspiratory airway pressure meter.
- 868.1800 Rhinomanometer.
- 868.1840 Diagnostic spirometer.
- 868.1850 Monitoring spirometer.
- 868.1860 Peak-flow meter for spirometry.
- 868.1870 Gas volume calibrator.
- 868.1880 Pulmonary-function data calculator.
- 868.1890 Predictive pulmonary-function value calculator.
- 868.1900 Diagnostic pulmonary-function interpretation calculator.
- 868.1910 Esophageal stethoscope.
- 868.1920 Esophageal stethoscope with electrical conductors.
- 868.1930 Stethoscope head.
- 868.1965 Switching valve (ploss).
- 868.1975 Water vapor analyzer.

Subpart C—Monitoring Devices

- 868.2025 Ultrasonic air embolism monitor.
- 868.2300 Bourdon gauge flowmeter.
- 868.2320 Uncompensated thorpe tube flowmeter.
- 868.2340 Compensated thorpe tube flowmeter.
- 868.2350 Gas calibration flowmeter.
- 868.2375 Breathing frequency monitor.
- 868.2380 Nitric oxide analyzer.
- 868.2385 Nitrogen dioxide analyzer.
- 868.2450 Lung water monitor.
- 868.2480 Cutaneous carbon dioxide (PcCO₂) monitor.
- 868.2500 Cutaneous oxygen monitor.
- 868.2550 Pneumotachometer.
- 868.2600 Airway pressure monitor.
- 868.2610 Gas pressure gauge.
- 868.2620 Gas pressure calibrator.
- 868.2700 Pressure regulator.